UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICH REINISCH, Derivatively on Behalf of BIOPURE CORPORATION,	Civil Action No. 04 10215 NG
Plaintiff,	
vs.	DERIVATIVE ACTION
THOMAS A. MOORE, CARL W. RAUSCH, DAVID N. JUDELSON, CHARLES A. SANDERS, M.D., C. EVERETT KOOP, M.D., DANIEL P. HARRINGTON and J. RICHARD CROUT, M.D.,	DEMAND FOR JURY TRIAL
Defendants,	MAGISTRATE JUDGE
-and-	
BIOPURE CORPORATION, a Delaware Corporation,	
Nominal Defendant.	

RECEIPT #
AMOUNT $150
SUMMONS ISSUED YES
LOCAL RULE 4.1
WAIVER FORM
MCF ISSUED
BY DPTY. CLK.
DATE 1/29/04

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTIES, ABUSE OF CONTROL, GROSS MISMANAGEMENT, WASTE OF CORPORATE ASSETS AND UNJUST ENRICHMENT

NATURE OF THE ACTION

1. This is a shareholder derivative action brought in the right of, and for the benefit of, nominal defendant Biopure Corporation ("Biopure" or the "Company") against its Board of Directors (the"Board") and certain top officers to remedy defendants' breaches of fiduciary duties and other violations of law which have inflicted millions of dollars in damages upon Biopure's reputation, goodwill and standing in the business community and have exposed it to millions of dollars in potential liability for violations of state and federal law. This action arises out of defendants' causing Biopure to file false financial statements and to issue misleading statements and conceal material facts from investors and the public concerning Hemopure®, one of the Company's primary products, between March 17, 2003 and December 24, 2003 (the "Relevant Period"). Defendants' misconduct has caused severe, irreparable, injury and damages to the Company, particularly to its reputation and goodwill in the investment and business community, and has virtually destroyed this once valuable franchise.

SUMMARY OF THE ACTION

2. Biopure is a biotechnology company that develops, manufacturers and markets oxygen therapeutics, a new class of pharmaceuticals that are intravenously administered to deliver oxygen to the body's tissues. The Company had developed two products, one of which is Hemopure® [hemoglobion glutamer - 250 (biovine)], which is an investigational product for the treatment of acutely anemic surgical patients and for the elimination, delay or reduction of red blood cell transfusions in these patients. Hemopure® is a human blood substitute made from refined cow hemoglobin which acts like red blood cells to deliver oxygen to the body. However, unlike donated blood, Hemopure® does not have to be matched to a patient's blood type.

3. On July 31, 2002, Biopure submitted a Biologic License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval to market Hemopure® in the U.S. for use in orthopedic surgery. On that date, the *Boston Globe* ran an indepth article questioning the Company's suspicious concealment of information concerning Hemopure's® status:

> Though Biopure completed its two Phase III trials in November 2000, the company has been extraordinarily secretive about the results. In a departure from common practice, it has declined to release the comprehensive results of the potentially pivotal experiments. Instead, it has disclosed bits and pieces of the results, none of which are definitive.
>
> "It's out of the ordinary," said Dr. Mark Monane, biotechnology and life sciences analyst for Needham & Co. in New York. "We generally expect to get the results of phase 2 trials, then phase 3 trials, then a filing to the FDA. I don't think there's a regulatory rule requiring it, but most investors would like to hear about the phase 3 data before the filing. In general, phase 3 trials are material events and there's a need to disclose the results to investors."

4. In September 2002, the Company received a grant from the U.S. Department of the Army to conduct clinical trials of Hemopure® for the treatment of trauma patients. In March 2003, the Company submitted a "trauma study protocol" to the FDA in connection with its plans to conduct a phase II clinical trial of Hemopure® for the treatment of trauma patients. At the time, this information was not revealed by Biopure to the public.

5. During the Relevant Period, the defendants continually represented they were optimistic of achieving FDA approval to market Hemopure® to orthopedic patients. However, unbeknownst to the public, as early as March 2003, the FDA had informed the defendants that the proposed clinical trials could not go forward, citing "safety concerns" arising from adverse event data submitted as part of the Company's BLA which sought FDA approval to market

Hemopure® to orthopedic surgery patients. Thus, the defendants were on notice that FDA approval of the BLA, which would allow the first commercial distribution, if any, of Hemopure® in the United States, was in serious jeopardy and would be delayed beyond the mid-2003 target date defendants had previously stated.

6. Finally, under the threat of civil litigation by the Securities and Exchange Commission ("SEC"), on December 24, 2003, after the close of the market on Christmas Eve, the defendants announced a potential SEC inquiry for securities fraud, and for the first time, disclosed material problems with is Hemopure® product and the FDA approval process. The defendants announced that:

> (1) On Monday, December 22, 2003, the Company had received a Wells Notice from the SEC. The SEC sends a Wells notice to a company or an individual after its staff has completed an investigation and its staff has completed an investigation and determined that sufficient wrongdoing has occurred to warrant civil charges being filed. The SEC sent a Wells notice to Biopure, defendant Moore and Howard Richman, the Company's former vice president of regulatory affairs, ***for failing to adequately disclose material information about Biopure's communications with the FDA concerning the Company's application***;
>
> (2) For the first time, that in March 2003, the Company had sought FDA permission to begin new clinical trial testing of Hemopure® in hospitalized trauma patients and that the FDA has repeatedly denied the request;
>
> (3) The FDA had refused to allow the study because of material "safety concerns" from the Company's Phase III orthopedic surgery trial;
>
> (4) The FDA had placed a "clinical hold" on any trauma trials, and requested more information, including additional animal studies, before Hemopure® could be tested in humans under trauma conditions; and
>
> (5) Despite Biopure's supplemental filings on July 30, 2003, the FDA again had denied Biopure's request that if lift its "clinical hold," barring any Hemopure® trauma trials.

7. In response to this news, the Company's common stock has fallen as low as under $2 per share in January 2004, from a Relevant Period high of over $8 per share in August and September of 2003, erasing over $266 million in market capitalization, or 75% of the Company's market value during the Relevant Period, and severely reducing the Company's financing options. As a result of the defendant's misrepresentations and nondisclosures concerning its communications with the FDA, Biopure's stock traded at artificially inflated prices during the Relevant Period. Certain insiders, including defendant Carl W. Rausch ("Rausch"), took advantage by selling hundreds of thousands of shares of his personally held stock for proceeds of nearly $1.6 million at prices as high as $7.53 per share.

8. As a direct result of this illegal course of conduct, the Company has been exposed to tens of millions of dollars in potential liability for violations the nation's securities laws and regulations and has been named in numerous federal securities class action lawsuits filed in the United States District Court for the District of Massachusetts, on behalf of investors who purchased Biopure's shares. These lawsuits allege that investors purchased shares of the Company based on false and materially misleading statements regarding the financial condition of the Company and that they have been significantly damaged thereby. Specifically, those actions allege that defendants caused Biopure to: (i) deceive the investing public regarding Biopure's business, operations, management and intrinsic value of Biopure common stock; (ii) be exposed to tens of millions of dollars in potential securities fraud liability for issuing a false and misleading registration statements and prospectuses during the Relevant Period in order to issue over 5.5 million common shares for over $35 million in proceeds; (iii) enable certain defendants and insiders to sell significant amounts of their personally-held shares of Biopure common stock

at artificially inflated prices; and (iv) cause Biopure shareholders to purchase Biopure securities at artificially inflated prices during the Relevant Period. Defendants also increased the Company's general and administrative costs by almost $2.3 million during the first nine-months of 2003, due in large part to defendants causing Biopure to take a substantial non-cash charge to fund certain directors' stock purchases and to pay of "recruiting" costs.

JURISDICTION AND VENUE

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 (a)(2) in that plaintiff and defendants are citizens of different states and the matter in controversy exceeds $75,000, exclusive of interest and costs. This Court also has supplemental jurisdiction pursuant to 28 U.S.C. §1367(a).

10. This action is not a collusive one designed to confer jurisdiction on a court of the United States which it would not otherwise have.

11. Venue is proper in the Court because nominal defendant Biopure is headquartered in this District and thus a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, occurred in this District. One or more of the defendants either resides in or maintains executive offices in this District, and defendants have substantial compensation in this District by engaging in numerous activities and conducting business here, which had an effect in this District.

PARTIES

12. Plaintiff Rich Reinisch is resident of the State of Missouri, is and was at relevant times complained of herein, a shareholder of nominal defendant Biopure.

13. Nominal defendant Biopure is a Delaware corporation with its principal executive

offices located at 11 Hurley Street, Cambridge, MA 02141.

14. Defendant Thomas A. Moore ("Moore") was, at all relevant times, a director of Biopure, its President and Chief Executive Officer ("CEO"). Moore is a citizen of New Jersey. As an officer and director of Biopure, Moore owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. But as late as July, 2002, when Biopure filed the Hemopure® FDA application, Moore had not begun working at Biopure full-time, despite being the Company's President and CEO. Moreover, as its President and CEO, Moore had also assumed important managerial responsibilities at Biopure which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Moore owed to Biopure and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As a result of his wrongdoing, Moore received a Wells Notice from the SEC and has been named as a defendant in numerous securities fraud lawsuits brought against the Company by its shareholders. In addition, Moore certified the Company's financial statements filed with the SEC during the Relevant Period including its Form 10-Q's without disclosing the adverse material information concerning the Company's communications with the FDA regarding Biopure and therefore Moore is a direct participant in the wrongdoing. Pursuant to his employment agreement with the Company, Moore receives an annual base salary of not less than $350,000. By virtue of his executive positions with Biopure, his longer term personal, professional and financial relationships with Sanders, Rausch, Judelson and the other members

of the Biopure Board, his stock sales and personal participation in the underlying misconduct, Moore is not disinterested, is not independent and could not have adequately considered a pre-suit demand to bring the allegations contained herein.

15. Defendant Rausch was, at all relevant times, Vice Chairman of Biopure and its Chief Technical Officer ("CTO"). Rausch is a citizen of Massachusetts. As Vice Chairman of Biopure, Rausch owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as CTO, Rausch had also assumed important managerial responsibilities at Biopure which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Rausch owed to Biopure and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As a result of his wrongdoing, Rausch has been named as a defendant in numerous securities fraud lawsuits brought against the Company by its shareholders. During the Relevant Period, Rausch engaged in massive insider trading disposing of 246,574 shares of his personally held Biopure stock for proceeds of $1,596,900. In 1984, Rausch co-founded Biopure with defendant David N. Judelson ("Judelson"). Rausch and Judelson are close friends and confidants. For example, Rausch sold some of his personally held Biopure stock to Judelson. Rausch and Judelson appointed Charles A. Sanders, M.D. ("Sanders") as Chairman and Moore CEO, President and as a director in 2002. Moreover, Judelson serves on Biopure's Compensation Committee which determines Rausch's salary, bonuses and stock options. By

virtue of his executive positions with the Company, his stock sales, his personal participation in the underlying misconduct, and his long term personal, professional and financial relationships with Sanders, Moore, Judelson and the other members of the Biopure Board, Rausch is not disinterested, is not independent and could not have adequately considered a pre-suit demand to bring the allegations contained herein.

16. Defendant Judelson was, at all relevant times, Vice Chairman of Biopure and a member of its Compensation Committee. Judelson is a citizen of New York. As Vice Chairman of Biopure, Judelson owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of its Compensation Committee, Judelson had also assumed important managerial responsibilities at Biopure which required him to be well informed about the day-to-day operations of the Company. Rather than fulfill these important fiduciary duties Judelson owed to Biopure and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. In 1984, Judelson co-founded Biopure with Rausch. Judelson and Rausch are close friends and confidants. For example, Rausch sold some of his personally held Biopure stock to Judelson. Rausch and Judelson appointed Sanders as Chairman and Moore as CEO, President and as a director in 2002. Moreover, Judelson serves on Biopure's Compensation Committee which determines Moore and Rausch's salary, bonuses and stock options. By virtue of his executive positions with the Company, his personal participation in the underlying misconduct and his extensive and long-term personal, professional, and financial

relationships with Rausch, Moore and Sanders, and the other members of the Biopure board, Judelson is not independent, is not disinterested and could not have adequately considered a pre-suit demand to bring the allegations contained herein.

17. Defendant Sanders was, at all relevant times, a director of Biopure, Chairman of its Compensation Committee and a member of the Nominating and Audit Committees. Sanders is a citizen of North Carolina. As Chairman of Biopure, Sanders owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as Chairman of its Compensation Committee and as a member of its Nominating and Audit Committees, Sanders had also assumed important managerial responsibilities at Biopure which required him to be well informed about the day-to-day operations of the Company, particularly, as a member of its Audit Committee, with ensuring that the Company's financial statements and corresponding press releases included all material information including the Company's communication with the FDA concerning Hemopure®. Rather than fulfill these important fiduciary duties Sanders owed to Biopure and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Sanders previously served as General Director of Massachusetts General Hospital and Professor of Medicine at Harvard Medical School, along with Douglas M. Hansell, M.D. who currently serves as Biopure's Vice President of Medical Affairs and served with Sanders at Massachusetts General Hospital and at Harvard. As a member of the Audit Committee, Sanders approved the Company's financial statements without

including the adverse material information concerning the Company's communications with the FDA regarding Hempoure and therefore Sanders is a direct participant in the wrongdoing. By virtue of his executive positions with Biopure, his personal participation in the underlying misconduct, and his extensive and long-term personal, professional and financial relationships with Moore, Rausch and Judelson, Sanders is not disinterested, is not independent and would not have adequately considered a pre-suit demand to bring the allegations contained herein.

18. Defendant C. Everett Koop, M.D. ("Koop") was, at all relevant times, a director of Biopure. Koop is a citizen of New Hampshire. As a director of Biopure, Koop owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Rather than fulfill these important fiduciary duties Koop owed to Biopure and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. Koop is a consultant for other companies in the pharmaceutical industry such as Biopure, regularly speaking on their behalf in front on regulatory bodies. For instance, in April 1999, Koop spoke at a Congressional Advisory Hearing on the national blood supply on behalf of Biopure, along with another former Biopure executive. In fact, on December 4, 1990, weeks before Koop joined the Board, Koop was hired by Biopure and was give the title of "Chairman of Scientific Advisory Committee" charged with advising the company on domestic, worldwide and military applications of its products and developing medical and scientific relationships with health organizations and medical centers around the world. By virtue current and past executive and/or

consulting positions with the Company, his personal participation in the underlying misconduct and his long-term personal, professional and financial relationships with Moore, Rausch, Sanders and Judelson, Koop would never authorize a suit for the claims asserted herein because it would threaten these relationships and jeopardize his livelihood.

19. Defendant Daniel P. Harrington ("Harrington") was, at all relevant times, a director of Biopure, Chairman of its Audit Committee and a member of the Nominating Committee. Harrington is a citizen of Ohio. As a director of Biopure, Harrington owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as Chairman of its Audit Committee and as member of its Nominating Committee, Harrington had also assumed important managerial responsibilities at Biopure which required him to be well informed about the day-to-day operations of the Company, particularly, as a member of its Audit Committee, with ensuring that the Company's financial statements and corresponding press releases included all material information including the Company's communication with the FDA concerning Hemopure®. Rather than fulfill these important fiduciary duties Harrington owed to Biopure and its shareholders he, upon information and belief, actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As Chairman and as a member of the Audit Committee, Harrington approved the Company's financial statements without including the adverse material information concerning the Company's communications with the FDA regarding Hemopure® and therefore Harrington is a direct participant in the wrongdoing. Harrington has served as President of HTV

Industries, Inc. ("HTV"), one of Biopure's venture capitalist, since 1991. HTV, along with Judelson and Moore, took part in the Company's April 2003 public offering in which it raised over $13 million. In the offering, HTV purchased 516,529 shares of the Company's common stock and warrants to purchase an addition 103,306 shares while Moore and Judelson each purchased 206,612 shares and warrants to purchase to an additional 41,322 shares. According to the Company's most recent Proxy Statement, Harrington owns 1,560,089 shares of Biopure or 4.7% of the Company's outstanding common stock which includes 1,498,219 shares and warrants to purchase 11,111 shares owned by HTV. By virtue of his close personal, professional and financial relationships with Rausch, Judelson, Sanders and Moore and the other members of the Biopure Board, his personal participation in the underlying misconduct, and his and HTV's purchases and ownership of substantial shares of Biopure's stock, Harrington could not adequately investigate and would never authorize a suit for the claims asserted herein.

20. Defendant J. Richard Crout, M.D. ("Crout") was, at all relevant times, a director of Biopure and a member of its Audit Committee. Court is a citizen of Maryland. As a director of Biopure, Crout owed a duty to the Company and its shareholders to be reasonably informed about the business and operations of the Company. Moreover, as a member of its Audit Committee, Crout had also assumed important managerial responsibilities at Biopure which required him to be well informed about the day-to-day operations of the Company, particularly, as a member of its Audit Committee, with ensuring that the Company's financial statements and corresponding press releases included all material information including the Company's communication with the FDA concerning Hemopure®. Rather than fulfill these important fiduciary duties Crout owed to Biopure and its shareholders he, upon information and belief,

actively participated in or knowingly encouraged, sponsored or approved many of the wrongful acts or omissions complained of herein, and/or breached his fiduciary duties to the shareholders of Biopure by purposefully, recklessly and/or negligently disregarding these wrongful acts or omissions. As a member of the Audit Committee, Crout approved the Company's financial statements without including the adverse material information concerning the Company's communications with the FDA regarding Hemopure® and therefore Crout is a direct participant in the wrongdoing. Crout owns Crout Consulting and is a pharmaceutical industry consultant, and his vocation is providing regulatory and drug development advice to pharmaceutical and biotechnology companies. Similarly, Crout and Sanders have long served together on the Trimeris board of directors. In 1994, Paul A. Miller was named to the newly-created position of Marketing Manager-Nutritional Products at MBf USA where it was announced he would work closely with Koop who had also recently joined MBf USA as "Chairman of its Advisory Board," to guide the development and global launch of the Company's vitamin supplement and nutritional products line. Prior to joining MBf USA, Miller had most recently served under Crout at as the Consumer Segment Product Manager for Boehringer Mannheim Corp., prior to Crout founding Crout Consulting. By virtue of his extensive and long-term personal, professional and financial relationships with Rausch, Moore, Sanders and Judelson and the fact that Crout's primary vocation is serving as a consultant pharmaceutical companies such as Biopure, he would never authorize a suit for the claims asserted herein because it would damage his personal, professional and financial relationships and could potentially jeopardize his livelihood.

21. The defendants identified above in ¶¶15-21 are collectively referred to hereinafter

as the "Individual Defendants."

FACTS

22. On July 31, 2002, Biopure submitted a BLA to the FDA seeking regulatory approval to market Hemopure® in the U.S. for use in orthopedic surgery. On that date, the Company issued a press release entitled "Biopure Submits Hemopure® Marketing Application to the U.S. FDA" that stated in part:

> Biopure Corporation today announced that it has submitted an electronic Biologic License Application (BLA) to the U.S. Food and Drug Administration (FDA) for its oxygen therapeutic Hemopure® [hemoglobin gultamer - 250 (bovine), or HBOC-201]. The company is seeking regulatory approval to market this pharmaceutical product in the United States for the treatment of the signs and symptoms of acute anemia in adult patients undergoing orthopedic surgery, and for the purpose of eliminating, delaying or reducing the need for red blood cells in these patients.

23. In September 2002, the Company received a $980,000 grant from the U.S. Department of the Army to fund a randomized, standard therapy-controlled, single center Phase II clinical trial in consenting trauma patients as a precursor to broader trials.

24. In March 2003, the Company submitted a "trauma study protocol" to the FDA in connection with its plans to conduct a Phase II clinical trial of Hemopure® for the treatment of trauma patients. However, at the time, this information was not revealed by Biopure to the public.

25. During the Relevant Period, the defendants continually represented they were optimistic of achieving FDA approval to market Hemopure® to orthopedic patients. However, unbeknownst to the public, as early as March 2003, the FDA had informed the defendants that the proposed clinical trials could not go forward, citing "safety concerns" arising from adverse

event data submitted as part of the Company's BLA which sought FDA approval to market Hemopure® to orthopedic surgery patients. Thus, the defendants were on notice that FDA approval of the BLA, which would allow the first commercial distribution, if any, of Hemopure® in the United States, was in serious jeopardy and would be delayed beyond the mid-2003 target date defendants had previously stated.

IMPROPER STATEMENTS MADE DURING THE RELEVANT PERIOD

26. On March 17, 2003, Biopure filed its quarterly report on Form 10-Q for the period ending January 31, 2003. The Form 10-Q, signed and certified by defendant Moore reported that the Company had a net loss of $0.36 per share during the first quarter fiscal 2003 compared to a net loss of $0.38 for the same period last year. In addition the Form 10-Q included the following representations concerning the Company's Hemopure® research and development efforts, stating in pertinent part as follows:

> Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation. These BLA support costs were $2,232,000 for the first fiscal quarter of 2003 and are expected to continue at approximately the same level ***until the middle of this calendar year, when the Company is hopeful that it will receive action by the FDA on the BLA....***
>
> ***If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004.*** We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure, the timing of the construction of additional capacity and other factors that may affect our ability to generate a profit from our research and development of Hemopure.

27. On or about March 25, 2003, Biopure issued a press release announcing that it has

raised $13.4 million in gross proceeds through the sale of 5,548,480 shares of its common stock at $2.42 per share. The press release stated in pertinent part as follows:

> Hemopure® [hemoglobin glutamer - 250 (bovine)] is approved in South Africa for the treatment of adult surgical patients who are acutely anemic and for the purpose of eliminating or reducing the need for allogenic red blood cell transfusion in these patients. Biopure's application to market Hemopure® in the United States for a similar indication in adult patients undergoing elective orthopedic surgery is currently being reviewed by the U.S. Food and Drug Administration....
>
> The previously announced $4.9 million in FY02/03 Congressional appropriations administered through the U.S. Army and anticipated $4 million in U.S. Navy funding from a Cooperative Research and Development Agreement (CRADA) ***for clinical trials of Hemopure® in trauma*** are project-specific funds independent from Biopure's reported cash on hand. Completion of the pivotal RESUS clinical trial of Hemopure® in trauma is contingent upon further funding. $908,900 of the Army funding is from Grant DAMD17-02-1-0697, for which the U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office.

28. On or about May 22, 2003, Biopure issued a press release announcing its financial results for the second fiscal quarter ended April 30, 2003. For the quarter, the Company reported a net loss of $0.35 per common share, compared with a net loss of $0.49 per common share, for the corresponding period in 2002. Regarding the FDA's pending approval of Biopure's Hemopure® BLA, the press release stated in pertinent part:

> Biopure is hopeful that in mid 2003 the FDA will complete its review and act on Biopure's biologic license application (BLA) to market Hemopure® in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery. As part of this review, the agency has inspected the company's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. Biopure has responded to all questions raised by the FDA to date.

29. On or about May 30, 2003, the Company issued a press release announcing that the FDA had notified Biopure that it will complete its review and act on the Company's BLA for

Hemopure® by August 29, 2003. Defendant Moore, on behalf of the Company, commented on the FDA's review process:

> "We're very pleased with the FDA's progress in reviewing our application[.] We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available as an alternative to red blood cell transfusion. We're also continuing our preparations to roll out the product to leading orthopedic surgery centers following approval."

30. On our about July 23, 2003, Biopure issued a press releasing announcing that it has raised $17.2 million in gross proceeds through the sale of 3,083,000 shares of its common stock at $5.58 per share.

31. On or about August 21, 2003, Biopure issued a press release announcing its financial results for the third fiscal quarter ended July 31, 2003. For the quarter, the Company reported a net loss of $0.28 per common share, compared with a net loss of $0.43 per common share, for the corresponding period in 2002. The press release included the following representations concerning the FDA's review of the Company's Hemopure® BLA, stating in pertinent part as follows:

> On July 30th, the FDA sent Biopure a letter stating that the agency has completed its review of the company's BLA to market Hemopure® in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The letter requests additional information and suspends the BLA review clock with 30 days remaining in the original review cycle. It does not request additional clinical trials.

32. On or about October 30, 2003, Biopure announced its plan to respond by June 30, 2004, to the FDA's questions regarding its BLA for Hemopure®. The press release stated that the Company has adjusted its operating plan to reduce expenses and conserve cash while it completes its written response to the FDA. The press release stated in pertinent part as follows:

> During the past two months the company has had several substantive interactions with the FDA to clarify the Agency's questions. Many of Biopure's responses have been completed. However, some require the retrieval of source medical documents and/or historical blood transfusion data from clinical trial sites in various countries, which will take several months to complete.

Defendant Moore, on behalf of the Company, commented, in pertinent part, as follows:

> "In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions[.] We view the Agency's questions as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure® in the United States as expeditiously as possible."

THE TRUTH IS REVEALED AND THE COMPANY IS SEVERELY DAMAGED

33. After the close of trading on December 24, 2003, at 5:52 p.m., the Individual Defendants caused the Company to issue a press release announcing that: (1) the Company, defendant Moore and a former Vice President had each received Wells Notices from the SEC related to the Company's inadequate disclosures concerning communications with the FDA about Hemopure®'s applications; and (2) in March 2003 - undisclosed to the public - the Company had filed an application with the FDA for the use of Hemopure® in clinical trauma studies, but that the FDA had repeatedly blocked the trial due to material safety concerns. Specifically, the Individual Defendants caused the Company to issue a press release entitled "Biopure Receives 'Wells Notice' From Securities and Exchange Commission" which stated in relevant part.

> Biopure Corporation reported that on December 22, 2003, it received a"Wells Notice" from the staff of the Securities and Exchange Commission (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the company. As permitted under the Wells process, Biopure intends to respond promptly and thoroughly in writing before the SEC staff formally decides what action, if any, to recommend. The company's chief executive officer and its former senior vice president of Regulatory and Operations also received Wells Notices.